

# **HUMAN IMMUNODEFICIENCY VIRUS (HIV) & HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)**

## **I. INTRODUCTION**

HIV is an RNA retrovirus that causes a chronic illness characterized by destruction of CD4 lymphocytes; over the course of years, the immune system is no longer able to replace these cells, and immune suppression leads to illness and death. The asymptomatic period between infection and immune suppression varies. With effective therapies, newly diagnosed individuals may have healthy lives lasting more than 25 years prior to progression to Acquired Immunodeficiency Syndrome (AIDS).

AIDS is one of the leading causes of death among women of reproductive age. The etiologic agent of AIDS is the human immunodeficiency virus (HIV). The transmission of HIV is by three primary routes: intimate contact with bodily secretions of infected individuals, exposure to blood or blood products infected with HIV, and perinatally from an infected mother to her fetus or infant. In women, the use of intravenous drugs, sexual contact with an infected partner and exposure to blood or body fluids from an infected person are the typical routes of transmission.

The state of Maryland has one of the highest rates of HIV/AIDS in women in the United States. In addition, perinatal HIV transmission is the most common route of HIV infection in children and is now the source of almost all AIDS cases in children in the United States. With early diagnosis of infected mothers and use of antiretroviral therapy, the transmission of HIV from mother to infant can be reduced to 2% or less. Although HIV is disproportionately found in the African-American and Hispanic communities and among poor, urban families, it is present across the state, in rural as well as urban areas, affluent as well as impoverished families.

Strategies available for dealing with HIV infection are primary prevention, through education that leads to changes in behavior, and secondary prevention through the identification of infected individuals and selected drug therapy to retard/prevent progression of the HIV infection.

## **II. HIV DISEASE**

- A. HIV disease is a progression of immune system damage leading to illness and/or death due to opportunistic infections, wasting, or neoplasms.
- B. The time it takes from HIV infection to the low CD4 lymphocyte count that define AIDS is called the incubation period.
- C. Two to four weeks after exposure to HIV, an individual may experience an acute mononucleosis-like syndrome. Symptoms include low-grade fever, fatigue, rash, myalgia, nausea/vomiting and diarrhea. Generalized lymphadenopathy may be seen even in women who are immune competent.
- D. The period of asymptomatic illness, during which time the immune system is still functioning, varies depending on when the diagnosis is made, in relation to when the infection began.

- E. The median incubation period from HIV infection until development of AIDS is estimated at approximately 10 years for young adults.
- F. The period from development of AIDS to HIV-related death is called the AIDS survival period.
- G. Women with declining immune competence may experience persistent or frequently recurring vaginal yeast infections and have more aggressive cervical changes when HPV is present. Women who develop pelvic inflammatory disease may be more likely to develop tubo-ovarian abscesses.

### III. TESTING AND DIAGNOSIS

Both the incubation period and the AIDS survival period can be prolonged with the effective use of antiretroviral therapy and bacterial prophylaxis. Early knowledge of HIV infection can optimize treatment and, by extension, the health of the individual. Diagnosing HIV infection during the acute phase of disease is particularly important. Persons with acute HIV infection are highly infectious, because HIV concentrations are extremely high in plasma and genital secretions following initial infection

**All clients should be offered the HIV screening test at every visit, because a substantial percentage of infected women (up to 40% in one study) are not aware that they are at risk.**

Persons should be notified that testing will be performed, but retain the option to decline or defer testing (an opt-out approach). Consent for HIV screening should be incorporated into the general informed consent for medical care in the same manner as other screening or diagnostic tests. A separate consent form for HIV testing is not recommended.

- A. HIV antibodies can be detected in most individuals 6-12 weeks after exposure. Many individuals are only diagnosed late in the course of infection.
- B. The use of risk factors is no longer an effective way to identify who should be tested.
- C. The Centers for Disease Control and Prevention recommend that HIV testing become part of routine health care for all adolescents and adults, and that all pregnant women be tested.
- D. All gynecologic clients are to be offered an HIV test.
- E. Education regarding HIV infection and the course of disease, risk behaviors, prevention of sexual transmission, and how the test will be performed, should be provided prior to testing.
- F. HIV testing should only occur with the knowledge and consent of the person tested. Anyone has the right to refuse to be tested.
- G. Standard testing procedures include:
  - 1. An initial screening test (enzyme immunoassay or EIA) followed by
  - 2. A confirmatory Western blot (WB) or an immunofluorescent assay (IFA).
- H. The HIV test is only considered positive when both the EIA and the WB are positive.
- I. False positive antibody tests can occur for any of several reasons, such as pregnancy antibodies or an autoimmune disease.
- J. Indeterminate results are reported when the WB/IFA shows abnormalities not consistent with an HIV diagnosis. This result may indicate someone is newly

- infected and in the process of sero-converting, or may be a response to another health problem.
- K. Indeterminate tests should be repeated, usually in 6 to 12 weeks.
  - L. If early infection is suspected base on symptoms (fever, malaise, lymphadenopathy, and skin rash) and/or history, antigen/antibody immunoassay or HIV RNA in conjunction with an antibody test is recommended. Persons suspected of recently acquired HIV infection should be referred immediately to an HIV clinical-care provider.

#### IV. MANAGEMENT AND CLIENT EDUCATION/COUNSELING

- A. At the initial family planning visit, all clients should receive specific education about the risk factors for acquiring HIV infection (Appendix A).
- B. The test is voluntary and confidential, and should be administered only after appropriate counseling and consent. Consent for HIV screening should be incorporated into the general informed consent for medical care in the same manner as other screening or diagnostic tests. A separate consent form for HIV testing is not recommended.
- C. Clients requesting or receiving testing should not be identified in a way that makes them unique in the clinic setting (i.e., charts flagged or clients referred to a single interviewer or location). Information regarding counseling and testing may be obtained from the AIDS Administration, Maryland State Department of Health and Mental Hygiene at 410- 767-5013.
- D. If the screening test (EIA) is positive, it must be followed by a confirmatory Western Blot or an immunofluorescent assay, before the patient is given the results.
- E. Clients who test negative should be provided with information on prevention of HIV infection (Appendix B).
- F. Clients who are HIV-infected should be provided with counseling that includes a discussion of the risks of perinatal transmission and allows the clients to make informed reproductive choices. (Appendix C) Inform the clients that treatment is available to reduce the risk of perinatal transmission of HIV.
- M. Refer HIV-positive clients to those providers who are skilled in the management and care of HIV-infected individuals.
- N. Persons suspected of recently acquired HIV infection should be referred immediately to an HIV clinical-care provider. Antiretroviral therapy during acute HIV infection is recommended, because it substantially reduces infectiousness to others, improves laboratory markers of disease, may decrease severity of acute disease, lowers viral set-point, reduces the size of the viral reservoir, decreases rate of viral mutation by suppressing replication, and preserves immune function

#### V. HIV INFECTION AND CONTRACEPTIVE MANAGEMENT

- A. In HIV-positive individuals, the family planning goal is high contraceptive efficacy, with low risk of woman-to-partner HIV transmission and low risk of partner-to-woman STI transmission. This goal is met by choices such as IUD or hormonal contraceptives IN ADDITION TO male or female condoms.
- B. IUD is a good choice for women with HIV. No known interaction exists between ARV therapy and IUD use. IUD insertion is classified as category 2 if the woman

is not clinically well or not receiving ARV therapy. Otherwise, both insertion and continuation are classified as category 1.

- C. Drug interactions may exist between certain hormonal contraceptives and antiretroviral medications (ARV). ARV's can increase or decrease serum levels of estrogen and progestins. Prior to initiation of these methods the CDC MEC and drug-specific labeling must be reviewed to see whether additional back-up methods of contraception or different methods of contraception need to be considered.
- D. The CDC Medical Eligibility Criteria should be reviewed for all women with HIV.

## VI. PRE-EXPOSURE PROPHYLAXIS, (PrEP)

The U.S. Public Health Service recommends that clinicians evaluate their male and female patients who are sexually active or who are injecting illicit drugs and consider offering PrEP as one prevention option to those whose sexual or injection behaviors and epidemiologic context place them at substantial risk of acquiring HIV infection.

- A. Pre-exposure prophylaxis, or PrEP, is a way for people who do not have HIV but who are at substantial risk (Appendix A) of HIV infection.
  - 1. Consists of daily use of medication (brand name Truvada) that contains two medicines (tenofovir and emtricitabine).
  - 2. When taken consistently, PrEP has been shown to reduce the risk of HIV infection in people who are at high risk by up to 92%. PrEP is much less effective if it is not taken consistently.
- B. Criteria for PrEP eligibility:
  - 1. Ongoing substantial risk of HIV infection
  - 2. Documented negative HIV test before prescribing PrEP
  - 3. No signs/symptoms of acute HIV infection
  - 4. Normal renal function, no contraindicated medications
  - 5. Documented hepatitis B virus infection and vaccination status
- C. For access to PrEP guidelines: <https://www.cdc.gov/hiv/risk/prep/index.html>
- D. PrEP is only for people who are at ongoing substantial risk of HIV infection.
- E. For people who need to prevent HIV after a single high-risk event of potential HIV exposure—such as unprotected sex, needle-sharing injection drug use, or sexual assault—there is another option called postexposure prophylaxis, or PEP. PEP must begin within 72 hours of exposure: [www.cdc.gov/hiv/basics/pep.html](http://www.cdc.gov/hiv/basics/pep.html)) for more information.

## VII. REPORTING

Maryland law requires provider and laboratory reporting of all cases of HIV infection. Reporting instructions and forms can be accessed via the Maryland DHMH: <http://phpa.dhmh.maryland.gov/Pages/what-to-report.aspx>

## VIII. FOLLOW-UP

- A. Women who test positive for HIV antibody should be provided with detailed education and counseling.
- B. Although a negative antibody test usually means a person is not infected, antibody tests cannot rule out infection from a recent exposure. The test should be repeated 3 and 6 months after the most recent exposure.
- C. HIV infected pregnant women should be referred to a site for care that can provide appropriate therapy and testing in order to prevent perinatal transmission.
- D. HIV-infected women should be advised not to breastfeed their infants, since breast milk can transmit infection to the baby.

## REFERENCES

- 1. CDC Medical Eligibility Criteria for Contraceptive Use. MMWR / Vol. 65 / No. 3 / July 29, 2016
- 2. CDC: Sexually Transmitted Disease Treatment Guidelines, 2015
- 3. AIDSInfo has the most recent guidelines and recommendations:  
<http://aidsinfo.nih.gov/>
- 4. National HIV/AIDS Clinicians Consultation Center (NCCC)
- 5. Perinatal HIV Hotline 1-888-448-8765  
<http://www.ucsf.edu/hivcntr/Hotlines/Perinatal.html>
- 6. Centers for Disease Control and Prevention [cdc.gov/hiv/](http://cdc.gov/hiv/)

## APPENDIX A

### **RISK FACTORS FOR ACQUIRING HIV INFECTION**

1. Intravenous drug use
2. Unprotected sexual activity of any kind, in heterosexual couples or men having sex with men
3. Current or previous multiple sexual partners or prostitution
4. Known sexual or needle-sharing exposure to an HIV-infected person
5. Having a partner who is also having sex with others or using intravenous drugs
6. History of or current sexually transmitted diseases, hepatitis, or tuberculosis

## APPENDIX B

### **COUNSELING FOR HIV NEGATIVE INDIVIDUALS**

1. Modifiable risk factors
2. Co-factors that increase risk of HIV transmission, such as infection with other STIs or sharing drug paraphernalia
3. Effectiveness of barrier contraceptives to prevent sexual transmission
4. Importance of regular testing since the test is for infection, not immunity

## APPENDIX C

### **COUNSELING FOR HIV-POSITIVE INDIVIDUALS**

1. Local resources for HIV care, and medical referral in order to institute appropriate care promptly
2. Natural history of HIV infection
3. Use of antiretrovirals to prolong healthy life span and reduce risk of transmission to a partner
4. Prevention of transmission by responsible sexual activities and/or avoidance of sharing drug paraphernalia and/or sharing potentially blood contaminated articles such as razors or toothbrushes
5. Prevention of mother-to-child transmission
6. Options for sexual partner notification and notification of needle-sharing partners; importance of counseling and testing for exposed individuals
7. Importance of telling health care providers about HIV status